K121464

5 510(k) SUMMARY

JUL 5 2012

DATE: March 5, 2012

OWNER:
Northstar Healthcare Holdings
70 Sir John Rogerson's Quay
Dublin 2, Ireland

OFFICIAL CORRESPONDENT:
Alex Nagy
Manager, Quality Systems and Regulatory Affairs
Cypress Medical Products LLC
1200 South Route 31
McHenry, IL 60050
Telephone: 815-385-0100
Fax: 815-385-0114

DEVICE NAME:

Trade Name:	Blue Powder Free Nitrile Examination Glove
Common Name:	Patient Examination Gloves
Classification:	Patient Examination Gloves
Class:	Class I
Product Code:	LZA

PREDICATE DEVICE(S):

Predicate 510(k)	Device Name	Indication	Clearance Date	Company
K071119	Nitrile Powder Free Examination Gloves (Blue, White)	The examination gloves is a disposable device intended for medical and dental purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	24 Jul 2007	GX Corporation SDN BHN, Selangor Darul Ehsan, Malaysia

DEVICE DESCRIPTION:

Powder free blue nitrile patient examination glove, tested for use with Chemotherapy drugs, that meets all the requirements of ASTM standard D6319, except for sterility requirements.

STATEMENT OF INTENDED USE:

The nitrile examination glove is a disposable device intended for medical purposes to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.

TECHNOLOGICAL CHARACTERISTICS:

The Blue Powder Free Nitrile Examination Glove is substantially equivalent to the predicate device with regard to physical characteristics, design, product features, and intended use. Both gloves are made with Nitrile using similar manufacturing processes.

ASSESSMENT OF NONCLINICAL DATA:

Characteristic	Standard	Device Performance
Dimension	ASTM D6319	Meets
Physical Properties	ASTM D6319	Meets
Freedom from Pinholes	ASTM D5151 & ASTM D6319	Meets
Powder Residual	ASTM D6124	Meets Results generated values below 2mg of residual powder
Biocompatibility	Primary Skin Irritation in rabbits (ISO 10993-10)	Gloves are non-irritating
	Dermal Sensitization in the guinea pig (ISO 10993-10)	Gloves do not display any potential for sensitization

CONCLUSIONS:

The Blue Powder Free Nitrile Patient Exam Glove meet the requirements of established standards ASTM D6319-10, ASTM D6124-06, ASTM D5151-06, and ISO 10993-10.

Based on the comparison of intended use, design, materials and performance, the Blue Powder Free Nitrile Patient Exam Glove are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 20 2012

NorthStar Healthcare Holdings
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K121464
Trade/Device Name: Blue Powder Free Nitrile Patient Exam Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: June 20, 2012
Received: June 21, 2012

Dear Mr. Devine:

This letter corrects our substantially equivalent letter of July 5, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K121464

Device Name: **Blue Powder Free Nitrile Patient Exam Glove**

Indications for Use: The examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Claverie-Wilson

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121464